

11-04-04

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PTO/SB/21 (08-03)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)		Application Number	08/573,569
		Filing Date	12/14/1995
		First Named Inventor	Maassab, Hunein F.
		Art Unit	1648
		Examiner Name	Parkin, Jeffrey
Total Number of Pages in This Submission	8	Attorney Docket Number	UM 2002.01

**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment / Reply  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):  <b>25 cited references and Return Receipt Postcard</b>		
<table border="1"><tr><td>Remarks</td><td></td></tr></table>			Remarks	
Remarks				

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	Bingham McCutchen LLP Antoinette F. Konski
Signature	<i>Antoinette F. Konski</i>
Date	November 2, 2004

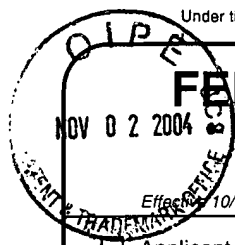
**CERTIFICATE OF MAILING**

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Typed or printed name	Peggy Nichols		
Signature	<i>Peggy Nichols</i>	Date	November 2, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 180

## Complete if Known

Application Number 08/573,569  
Filing Date 12/14/1995  
First Named Inventor Maassab, Hunein F.  
Examiner Name Parkin, Jeffrey  
Art Unit 1648  
Attorney Docket No. UM 2002.01

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money ☐ Other ☐ None  
Order

☒ Deposit Account:

Deposit  
Account  
Number 50-2518

Deposit  
Account  
Name Bingham McCutchen LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments  
☐ Charge any additional fee(s) during the pendency of this application  
☐ Charge fee(s) indicated below, except for the filing fee  
to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$ ) 0

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims	Fee from below	Fee Paid
Total Claims	20 **	0	X	0
Independent Claims	3 **	0	X	0
Multiple Dependent			X	0

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ ) 0

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ ) 180

## SUBMITTED BY

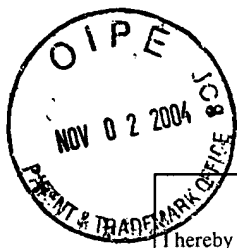
Complete (if applicable)

Name (Print/Type) Anjournette F. Kongsu  
Registration No. (Attorney/Agent) 34, 202  
Telephone (650) 849-4950  
Signature [Signature]  
Date November 2, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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Dated: November 2, 2004

Peggy Nichols  
Peggy Nichols

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

Maassab, Hunein F.

Serial No.: 08/573,569

Filing Date: 12/14/1995

For: COLD-ADAPTED INFLUENZA VIRUS

Examiner: Parkin, Jeffrey

Group Art Unit: 1648

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached form PTO/SB/08b are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. The Examiner is requested to make this document of record.

**I. Timing of the Information Disclosure Statement:**

This Information Disclosure Statement is filed:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.
- ☐ Before the mailing date of a first Office action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-2518 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).

11/05/2004 CNGUYEN 00000053 502518 08573569

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This Information Disclosure Statement is filed:

- ☒ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first. A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

This Information Disclosure Statement is filed:

- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☒ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

## II. Copies of the Cited Items:

- ☒ Copies of all of the items listed on the attached Forms PTO/SB/08b are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO/SB/08a & PTO/SB/08b are enclosed:
- ☐ Copies of all other items not listed above and listed in the attached Form PTO/SB/08a is not supplied in accordance with 37 CFR 1.98(a)(2).
- ☐ Copies of those items which are marked with an asterisk (\*\*) in the attached Form PTO/SB/08 were cited in a foreign examination report in a related case.

### III. Concise Explanation of Relevance:

- ☒ A concise explanation of relevance of the items listed on Forms PTO/SB/08 is not given.
- ☐ A concise explanation of relevance of [some of] the items listed on Form PTO/SB/08 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached).

### IV. Related Applications:

- ☐ Applicants bring to the Office's attention the following related, co-pending application(s):

### V. Conclusion:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

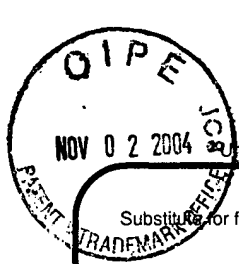
It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO/SB/08 with initials or other appropriate marks. The Commissioner is hereby authorized to charge Deposit Account No. 50-2518, billing reference number: 2023980-7009813001 for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

Dated: November 2, 2004

By: Antoinette F. Konski  
Antoinette F. Konski  
Registration No. 34,202

Bingham McCutchen LLP  
Three Embarcadero Center, Suite 1800  
San Francisco, California 94111-4067  
Telephone: (650) 849-4950  
Facsimile: (650) 849-4800



Substitute for form 1449B-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet **1** of **2****Complete if Known**

Application Number	08/573,569
Filing Date	12/14/1995
First Named Inventor	Hunein F. Maassab
Art Unit	1648
Examiner Name	Parkin, Jeffrey
Attorney Docket Number	UM 2002.01

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published
	1	ALEXandrova, G. I., et al., "Laboratory properties of cold-adapted influenza B live vaccine strains developed in the US and USSR, and their B/Ann Arbor/1/86 cold-adapted reassortant vaccine candidates" (1990) <i>Vaccine</i> 8:61-64
	2	BELSHE, R.B., et al. "Immunization of Infants and Young Children with Live Attenuated Trivalent Cold-Recombinant Influenza A H1N1, and B Vaccine" (1992) <i>J. Infectious Diseases</i> 165:727-732
	3	CLAVO, A.C., et al., "A persistent infection in MDCK cells by an influenza type B virus" (1993) <i>Virus Research</i> 29:21-31
	4	CLEMENTS, M. L., et al., "Evaluation of Bovine, Cold-Adapted Human, and Wild-Type Human Parainfluenza Type 3 Viruses in Adult Volunteers and in Chimpanzees" (1991) <i>J. of Clinical Microbiology</i> 29:1175-1182
	5	CLEMENTS, M. L., et al., "Evaluation of the Infectivity, Immunogenicity, and Efficacy of Live Cold-Adapted Influenza B/Ann Arbor/1/86 Reassortant Virus Vaccine in Adult Volunteers" (1990) <i>J. of Infectious Diseases</i> 161:869-877
	6	EDWARDS, K.M., et al., "Safety and Immunogenicity of Live Attenuated Cold-Adapted Influenza B/Ann Arbor/1/86 Reassortant Virus Vaccine in Infants and Children" (1991) <i>J. of Infectious Diseases</i> 163:740-745
	7	GORSE, G.J., et al., "Superiority of Live Attenuated compared with Inactivated Influenza A Virus Vaccines in Older, Chronically Ill Adults" (1991) <i>Chest</i> 100:977-984
	8	KARRON, R.A., et al., "A Live Attenuated Bovine Parainfluenza Virus Type 3 Vaccine Is Safe, Infectious, Immunogenic, and Phenotypically Stable in Infants and Children" (1995) <i>J. of Infectious Diseases</i> 171:1107-1114
	9	MAASSAB, H.F., et al., "Cold-Adapted Influenza Viruses for Use as Live Vaccines for Man" (1990) <i>Viral Vaccines</i> 203-242
	10	MAJDE, J.A., et al., "Detection of toxic viral-associated double-stranded RNA (dsRNA) in influenza-infected lung" (1991) <i>Microbial Pathogenesis</i> 10:105-115
	11	Sequential Analysis of the V3 Loop in HIV-1 From A Pediatric Population
	12	MASSEY J., et al., Abstract from General Mtg. "Genetic Variability in the HIV-1 Principle Neutralizing Domain from North American and African Isolates" (1993)
	13	POWERS, D.C., et al., "In Elderly Persons Live Attenuated Influenza A Virus Vaccines So Not Offer an Advantage over Inactivated Virus Vaccine in Inducing Serum or Secretory Antibodies of Local Immunologic Memory" (1991) <i>J. of Clinical Microbiology</i> 29:498-505
	14	RISER, B.L., et al., "Differential Interaction of virulent and Attenuated Influenza Virus Strains with Ferret Alveolar Macrophages: Possible Role in Pathogenicity" (1990) <i>J. of Infectious Diseases</i> 161:699-705
	15	SHAW, M.W., et al., "New Aspects of Influenza Viruses" (1992) <i>J. of Clinical Microbiology</i> 5:74-92
	16	SNYDER, M.H., et al., "A 36 nucleotide deletion mutation in the coding region of the NS1 gene of an influenza A virus RNA segment 8 specifies a temperature-dependent host range phenotype" (1990) <i>Virus Research</i> 15:69-84
	17	SNYDER, M.H., et al., "Attenuation and Phenotypic Stability of Influenza B/Texas/1/84 Cold-Adapted Reassortant Virus: Studies in Hamsters and Chimpanzees" (1989) <i>J. of Infectious Diseases</i> 4:604-610
	18	Steinhoff et al. (1992) "Cold-Adapted Live Attenuated Influenza Virus Vaccine is Safe and Immunogenic in 2-5 Month Old Infants" Research Paper, Mtg of Am. Ped. Society, Ped. Res. 31(2) 179A
	19	TREANOR, J.J., et al., "Protective Efficacy of Combined Live Intranasal and Inactivated Influenza A Virus Vaccines in the Elderly" (1992) <i>Annals of Internal Medicine</i> 117:625-633
	20	TREANOR, J.J., et al., "Evaluation of Live Attenuated Cold-Adapted Influenza B/Yamagata/16/88 Reassortant Virus Vaccine in Healthy Adults" (1993) <i>J. of Infectious Diseases</i> 168:455-459
	21	VAN WYKE, K.L., et al., "Antibody Responses of Humans and Nonhuman Primates to Individual Antigenic Sites of the Hemagglutinin-Neuraminidase and Fusion Glycoproteins after Primary Infection or Reinfection with Parainfluenza Type 3 Virus" (1990) <i>J. of Virology</i> 64:3833-3843
	22	VAN WYKE, K.L., et al., "Attenuation of Bovine Parainfluenza Virus Type 3 in Nonhuman Primates and Its Ability to Confer Immunity to Human Parainfluenza Virus Type 3 Challenge" (1988) <i>J. of Infectious Diseases</i> 157:655-662

Complete if Known

NOV 02 2004

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

Application Number	08/573,569
Filing Date	12/14/1995
First Named Inventor	Hunein F. Maassab
Art Unit	1648
Examiner Name	Parkin, Jeffrey
Attorney Docket Number	UM 2002.01

23	DOWLING-WHITAKER, P., et al., "The Genes Associated with Trans-dominance of the Influenza A Cold-Adapted Live Virus Vaccine" (1901) <i>Virology</i> 180:81-87	
24	DOWLING-WHITAKER, P., et al., "Dominant-Negative Mutants as Antiviral Agents: Simultaneous Infection with the Cold-Adapted Live-Virus Vaccine for Influenza A Protects Ferrets from Disease Produced by Wild-Type Influenza A" (1991) <i>J. of Infectious Diseases</i> 164:1200-1202	
25	YAMANE N., et al., "(1992) Conf. Paper 32nd Interscience Conf. on Micro 32(0) Oct. 11 to Oct. 14, (1992), "Five-Season Evaluation of Cold Adapted Line Influenza Vaccines Among Japanese Volunteers Against Natural Epidemics"	
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Examiner's  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. This information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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